



UNITED STATES PATENT AND TRADEMARK OFFICE

M'
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,083	02/20/2004	Rance A. Winkler	101360-68	7018
21125	7590	10/05/2004	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			VENIAMINOV, NIKITA R	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/784,083	Applicant(s) WINKLER ET AL.	
	Examiner Nikita R Veniaminov	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-15 is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/20/04 & 6/4/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 02/20/2004 and 06/04/2004 are being considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities: The Priority information on page 1, line 4 should be updated as follows: the phrase “, now is a Patent No. 6,695,760 B1” should be inserted after the phrase “2002”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Apple et al. (US 6,120,540). Apple et al. ('540) teach a system for combined surgical and radiation treatment of diseases of a load bearing portion of a patient's body, comprising:

(Claim 1) a structural support adapted to fit in an interstitial space in a load bearing portion of a patient's body (see Figure 3(10); column 2, lines 29-30 and column 3, lines 24-26) and to structurally stabilize the load bearing portion (see abstract; Figure 3(10); column 2, lines 29-30 and column 3, lines 24-26), the structural support defining an internal space (see Figure 6(60) and column 4, lines 21-31); a radiation source positionable within the internal space for delivering radiation to tissue surrounding the interstitial space (see Figure 6(60) and column 4, lines 21-31);

(Claim 2) the system further comprising a shield, the shield being adapted to shield radiation sensitive tissue from a portion of the radiation (see column 3, lines 48-55; Figure 3(22 and 24); column 3, lines 63-67 and column 4, lines 1-7);

(Claim 3) wherein the structural support is configured to fit within a cavity (a surgically replaced hip joint) in a patient's bone (see Figure 3 and column 2, lines 29-39);

(Claim 6) wherein the radiation source is configured to provide an asymmetric radiation dose within the tissue surrounding the interstitial space so that radiation sensitive tissue surrounding the interstitial space receives a lesser dose (see column 4, lines 1-20 and column 5, lines 30-38);

(Claim 7) wherein the structural support and the radiation source are adapted so that the radiation source is positioned at a predetermined distance apart from tissue surrounding the cavity so as to provide a prescribed absorbed

dose of radiation to the surrounding tissue to a predetermined depth (see column 3, lines 24-33 and column 5, lines 30-38).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US 5,015,247), cited by Applicant in view of Apple et al. (US 6,120,540). Michelson ('247) teaches a system for surgical treatment of diseases of a load bearing portion of a patient's body, comprising:

(structural limitations of the independent claim 1 and dependent claim 4) a structural support implant) (50) adapted to fit within a cavity in a patient's spine (vertebrae) (see Figure 5 where the structural support (50) is placed in the cavity of patient's vertebrae, which is depicted as V) and to structurally stabilize the load bearing portion (see column 5, lines 66-68 and column 6, lines 1-3), the structural support defining an internal space (61);

(Claim 5) wherein a portion of the structural support adapted to be positioned adjacent a patient's spine is formed from a radio-opaque material, preferably Titanium (see column 8, lines 40-43); the radio-opaque material (Examiner states, that Titanium is inherently radio-opaque material, and is

Art Unit: 3736

capable, or adapted to shield the patient's surrounding tissues of organs from radiation) is adapted to shield the patient's spinal cord from radiation, but he does not teach a radioactive source positionable within the internal space for delivering radiation to tissue surrounding the interstitial space.

However, Apple et al. ('540) an implant system (10) or a structural support adapted to fit an interstitial space in a load bearing portion of a patient's body (hip joint); a radiation source positionable within an internal space for delivering radiation to tissue surrounding the interstitial space (see Figure 6(60) and column 4, lines 21-31).

Without a showing of unexpected results or criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Michelson ('247) by the system of Apple et al. ('540) in order to inhibit heterotopic ossification, as taught by Apple et al. ('540).

Allowable Subject Matter

7. Claims 8-15 are allowed.
8. The following is a statement of reasons for the indication of allowable subject matter: Michelson (US 5,015,247) cited by Applicant, teaches an artificial spinal implant, which when placed between two adjacent vertebrae directly participates and is incorporated in the ensuring fusion; and a method of implantation said implant (see abstract and column 6, lines 34-68). Winkler et al. (WO 01/43826 A1) cited by Applicant, teach an interstitial brachytherapy

Art Unit: 3736

apparatus for delivering radioactive emissions in an asymmetric fashion to target tissue surrounding a surgical extraction site; an asymmetric radiopaque shielding between the radiation source and the target tissue and a surgical procedure using the apparatus (see abstract; page 3, lines 16-32 and page 4, lines 1-29). Brodke et al. (US 6,790,233) teach an improved ceramic bone graft for human implantation, such as a spinal fusion cage for implantation into the inter-vertebral space between two adjacent vertebrae (see abstract). Hochschuler et al. (US 6,740,093) teach an implantable container, used to stabilize or restore height in a vertebral body. After insertion the container is filled with a bone filler material such as bone cement (see abstract). Henderson et al. (US 6,665,555) teach a system and method for delivery of high dosage of radiation to a targeted spinal area for treating spinal metastases, that allows for the precise delivery of high dosage of radiation while minimizing or avoiding the delivery of radiation to non-targeted sites (see abstract and column 2, lines 25-30).

However, none of the prior art, either alone or in combination, teaches or suggests a method for treating metastases in a patient's spine, as claimed, comprising: placing a radiation source within a structural support, placed within an interstitial space in the spine.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brandau et al. ('379); Uk ('128); Ferree ('883);

Art Unit: 3736

Hochschuler et al. ('093); Beyar et al. ('7625); Brodke et al. ('233); Winkler et al. ('760); Henderson et al. ('555); McKay ('586) and Winkler et al. ('555).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nikita R Veniaminov
Examiner
Art Unit 3736



SAMUEL G. GILBERT
PRIMARY EXAMINER

September 27, 2004.